III. REMARKS

With the entry of the foregoing amendments, claims 29-31, 45-46 and 54-93 are pending in the present application. Claims 29, 31, 45, 46, 54, 60, 62, 63, 64, 65, 73, 75, and 76 have been amended. Claims 56, 57, 59, 61, 67-70, 74, and 77 are cancelled. Claims 78-93 are newly added. Claims 1-28, 32-44 and 47-53 were withdrawn from consideration or being drawn to non-elected inventions. Claims 29-31, 45-46, and 54, 55, 58, 60, 62-66, 71-73, 75-76 and 78-93 will be examined on their merits.

In the Office Action, objection is made to claims 57, 65, 75, and 77 under 37 CFR 1.821(d), which requires the use of the assigned sequence identifier (e.g. SEQ ID. NO: X) in all instances where the description of a patent application discusses sequences. Claims 29, 45, 46, 56, 57, 62, 64, 65, 67, 73-77and all subsequent dependent claims also stand variously rejected under 35 USC §112, second paragraph as being vague and indefinite. Claims 29-31, 45-46, 54, 56-62, 64-70, and 73-77 stand variously rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description of the claimed invention and enablement. Claims 57, 65, and 75 stand rejected under 35 U.S.C. 102(b) as being anticipated by Grattapaglia *et al.* (1995, W09519697) and Baxter-Lowe, L.A. (1996, U.S. Patent 5,545,526). Claims 29, 31, 45-46, 54, 56-59, 61-62, 64-66, and 76-77 stand rejected under 35 U.S.C. 102(b) as being anticipated by Oommen *et al.* (1994, *The Plant Cell* 6:1789-1803). Claims 29, 31, 45, 46, 54, 56-59, 61, 62, 64-70, 76, and 77 stand rejected under 35 U.S.C. 102(e) as being anticipated by Xue *et al.* (filed Sept. 9, 1996 U.S. Patent 6,420,629). All rejections are respectfully traversed. Applicants respectfully request reconsideration and withdrawal of all the rejections, and allowance of the claims in view of the foregoing amendments and for the reasons set forth below.

A. Election with traverse

The Examiner asserts that because the Applicants allegedly did not distinctly and specifically point out the errors in the restriction requirement, Paper No. 16, Applicants' election was treated as an election without traverse (MPEP 818.03(a)). Applicants respectfully submit that in Paper No. 18, Group V, claims 29-31 and 45-46 were provisionally elected with traverse. (See Paper No. 18, page 2, 1st¶). Also, it is submitted that Applicants distinctly and specifically pointed out the errors in the restriction requirement and made a bona fide attempt to advance the application. (See Paper No. 18, page 2, last ¶ through page 3.).

B. Allowable Subject Matter

Applicants acknowledge that claims 30, 55, 63, and 71-75 stand free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:5 that specifies expression in xylem cells and further comprises 5' flanking DNA, a cis-acting element, and a box P, A, or L sequence motif. Applicants thank the Examiner for his indication that, although, claims 55 and 63 are objected to for depending on rejected base claims, claims 55 and 63 would be allowable if rewritten in independent form, and that claims 71 and 72 are in condition for allowance.

C. Amendments to Claims

Claims 29, 31, 45, 46, 54, 60, 62, 63, 64, 65, 73, 75, and 76 have been amended herein for clarification purposes only. Claim 29 was amended to recite the specific regulatory sequence --SEQ ID NO:15--. Claims 45, 46, and 73 were amended to recite the lignin-specific nature of the 4CL regulatory sequence. Claims 45, 46, 62, 63, and 64 were amended to replace the term "control" with the term --regulatory sequence--. Claims 64, 65 and 75 were amended to replace the cis-acting elements with different sequence identifiers. Support for claiming specific transcriptional regulatory sequences (i.e., SEQ ID NOs. 5, 15, 16, and 17) can be found for example in the Sequence Listing and at page 28, lines 3-7 of the specification, as originally filed. Also, other regulatory sequence related characteristics (i.e., lignin-specificity or tissue–specificity) can be found for example at page 26, line 15 to page 31, line 21 of the specification, as originally filed. Also, claims 31 and 54 were amended to correct a minor grammatical error. Claim 60 was amended to recite that the expression cassette open reading frame can include either 4CL or another gene. Applicants respectfully submit that no new matter was added to the application.

D. Newly added claims

New claims 78-93 have been added herein for clarification purposes only. Applicants respectfully submit that new claims 78-93 are all fully supported by the contents of the specification, as originally filed. Specifically, support for claiming specific transcriptional regulatory sequences (i.e., SEQ ID NOs. 5, 15, 16, and 17) can be found, for example, in the Sequence Listing and at page 28, lines 3-7 of the specification, as originally filed. Also, other regulatory sequence-related characteristics (i.e., lignin-specificity or tissue–specificity) can be found, for example, at page 26, line 15 to page 31, line 21 of the specification, as

originally filed. Applicants respectfully submit that the newly added claims add no new matter to the application.

E. Rejection of Claims

1. Claims 29, 45, 46, 56, 57, 62, 64, 65, 67, 73-77 and All Subsequent Dependent claims Stand Rejected Under 35 USC §112, Second Paragraph.

The Office Action asserts that claims 29, 45, 46, 56, 57, 62, 64, 65, 67 and 73-77 and all subsequent dependent claims are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action asserts that claims 29, 45, 46, and 56 are indefinite in the recitation of the phrase "transcriptional regulatory region". Applicants submit that claims 29, 45 and 46 have been amended as set forth herein above to further clarify the phrase "transcriptional regulatory region". Claim 56 has been cancelled.

The Office Action asserts that claim 31 is indefinite in the recitation of the phrase "directs expression of a linked segment to the xylem", given that the use of the phrase "to the xylem" suggests that the regulatory sequence is regulating transport of the molecule, rather than an indication of transcription at that site. Claim 31 has been amended to replace the phrase "to the xylem" with the phrase --in the xylem-- as suggested by the Examiner for clarification purposes only.

The Office Action asserts that claim 54 is indefinite in the recitation of the phrase "gene of interest". Claim 54 has been amended to delete the phrase "of interest" as suggested by the Examiner for clarification purposes only.

Claim 56 requires the article "a" before "promoter fragment". Applicants submit that claim 56 has been cancelled for further clarity.

The Office Action asserts that claims 56, 74, 76, and 77 are indefinite in the recitation "promoter fragment" or "gene promoter". Claims 56, 74 and 77 have been cancelled for further clarity. Claim 76 has been amended to delete the phrase "a promoter fragment thereof", also to provide further clarity to the claim.

The Office Action asserts that claims 57, 65, 75, and 77 are indefinite in the recitation "a cis-acting element". Claims 57 and 77 have been cancelled for further clarity. Claims 65 and 75 have been amended to recite the sequence identifiers, to provide further clarity to the claims.

The Office Action asserts that claims 62 and 64, are indefinite in the recitation of "transcriptional control region". Dependent claims 62 and 64 have been amended to delete language as to xylem specificity, and to recite the sequence identifiers, as set forth hereinabove, to provide further clarity to the claims, respectively.

The Office Action asserts that claim 67 is indefinite in the recitation "4CL promoter", since it is unclear what that is. Claim 67 has been cancelled for further clarity.

The Office Action asserts that claims 73 and 74 are indefinite in the recitation "5' flanking region". Claim 73 has been amended to recite the lignin-specificity characteristic and to delete the "5' flanking region" language for further clarity. Claim 74 has been cancelled for further clarity.

The Office Action asserts that claims 57, 65, 75, and 77 are an improper Markush group as they fail to follow the prescribed format as noted in MPEP 2 173.05(h). Claims 57 and 77 have been cancelled for further clarity. Claims 65 and 75 have been amended to recite the sequence identifiers, as set forth hereinabove, to provide further clarity to the claims. Also, support for the above-cited claim amendments can be found for example at page 26, line 15 to page 31, line 21 of the specification, as originally filed.

Accordingly, Applicants respectfully submit that, based on the amendment of the subject claims, the rejection has been obviated.

2. Rejection of Claims 29-31, 45, 46, 56-62, 64-70, and 73-77 Under 35 USC §112, First Paragraph.

i) Written Description

Claims 29-31, 45, 46, 56-62, 64-70, and 73-77 stand rejected under 35 USC §112, first paragraph. The Office Action asserts that the specification does not contain a written description of the claimed invention which would reasonably convey to one skilled in the art that the inventor(s) had possession of the claimed invention at the time the application was filed. The Office Action further asserts that although Applicants have isolated "an aspen 4-coumarate Co-enzyme A ligase promoter from the Pt4CL1 genomic clone of SEQ ID NO:5 and demonstrated that it specified expression in xylem tissues of the leaf mid-rib and root of tobacco plants," Applicants have allegedly not identified structural and functional "features unique to Pt4CL1 genomic clone promoter of SEQ ID NO:5 or any 4-coumarate Co-enzyme A ligase promoter from aspen nor from any plant."

The Office Action also asserts that the holding of University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997) (cited on page 6 of the Office Action, September

13, 2002) is pertinent in the alleged deficiency of the instant application. The Office Action states that the Federal Circuit has recently stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants submit that while the above-recited teaching from University of California v. Eli Lilly and Co., provides guidance as to the adequacy of a written description with respect to the relationship between similar proteins among different species, it does not account for or address sufficient evidence as to plant transcriptional regulatory sequences.

As to the rejection, in the interest of advancing prosecution, Applicants have amended independent claims 29, 45 and 46 to more clearly identify what Applicants consider to be their invention and to recite what is, in fact, evident from the application as filed. Specifically, independent claims 29, 45 and 46 have been amended for clarification to recite the sequence identifiers (which correspond to the structural sequence information in the sequence listing) and lignin-specific nature of the 4CL transcriptional regulatory sequence (i.e., functional information). All amendments are fully supported in the specification as noted herein above. As such, all claims that depend from independent claims 29, 45 and 46 also meet the written description requirements of 35 USC §112, first paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

In summary, the key issue is whether Applicants have provided an adequate written description of their claimed method in accordance with the requirement of § 112, 1st ¶, i.e., whether the skilled artisan would have recognized that Applicants were in possession of their claimed 4CL transcriptional regulatory sequences at the time the application was filed. Applicants submit, from their specification that one of ordinary skill in the art would have recognized that Applicants were in possession of the claimed 4CL transcriptional regulatory sequences. For reasons set forth above, Applicants respectfully submit that claims 29-31, 45, 46, 56-62, 64-70, and 73-77 are more than adequately described by the specification as required by 35 U.S.C. § 112, first paragraph, and respectfully request that this rejection be reconsidered and withdrawn.

ii) Scope of Enablement

Claims 29-31, 45, 46, 56-62, 64-70, and 73-77 stand rejected under 35 USC §112, 1st ¶. The Office Action asserts that the specification, while being enabling for claims limited to an isolated and purified DNA molecule comprising the transcriptional regulatory region as

shown in SEQ ID NO:5, which is characterized by having promoter activity in the xylem of the stem, of the leaf mid-rib and in the root of transformed tobacco plants, the specification allegedly, among other things, does not reasonably provide enablement for claims broadly drawn to an isolated and purified DNA molecule, an expression cassette comprising a DNA segment comprising a transcriptional regulatory region of any plant 4-coumarate Co-enzyme A ligase gene, and a method of expressing a DNA segment in all the xylem cells of any plant. Thus, the Office Action asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is respectfully submitted, however, that adequate enablement and guidance for one skilled in the art to practice the claimed method in all plants is provided, without requiring undue experimentation. Specifically, Applicants respectfully submit that they have provided enablement for an isolated and purified DNA molecule, an expression cassette comprising a DNA segment comprising a transcriptional regulatory region of any plant 4CL gene, and a method of expressing a DNA segment in xylem cells of a plant by (1) amending the pertinent claims to clarify their claimed invention hereinabove (see amended claims 29, 31, 45, 46, 54, 60, 62, 63, 64, 65, 73, 75, and 76; cancelling claims 56, 57, 59, 61, 67-70, 74, and 77, and adding new claims 78-93); (2) demonstrating use of the claimed invention in more than one plant species (see specification at page 26-31 directed to the 4CL promoter); and (3) guiding one skilled in the art on how to select a lignin-specific, 4CL transcriptional regulatory region to practice the claimed invention (also, see specification at page 26-31 directed to the 4CL promoter).

Additionally, given the very high level of skill in this art area and the detail in which materials, methods, and results are presented in the application, practitioners in the art would be well-equipped to use the 4CL (lignin-specific) transcriptional regulatory region, either SEQ ID NO:5, containing either all of the three cis-acting elements or at least containing SEQ ID NO:15 to alter lignin and the claimed lignin-related characteristics. In fact, in the recently issued U.S. Patent No. 6,303,847 (hereinafter "the Nippon patent" copy attached for convenience) filed on March 31, 1999, it is disclosed that SEQ ID NO:5 (i.e., CTTTACCAACCCCCATC in Table 1) corresponding to the SEQ ID NO:15 of the present invention is a common regulatory sequence where transcription factors bind to achieve altered plant characteristics by modulating the 4CL gene expression. The Nippon patent provides evidence of the state of the art, specifically that 4CL regulatory elements such as SEQ ID NO:15 regardless of what plant they are introduced to are functionally important for

altering lignin-related characteristics. As such, one skilled in the art using a 4CL transcriptional regulatory region containing at least SEQ ID NO:15 of the present application will be able to replicate the lignifying tissue-specific expression profile in all plants as recited in the claims or disclosed in the specification.

In other words, because of the lignin-specific, 4CL promoter deletion studies disclosed in the specification, among other evidence, (see page 27, line 7-13) Applicants have adequately enabled one skilled in the art to prepare transgenic plants with altered lignin-related characteristics via use of SEQ ID NO:5, containing either all of the three cis-acting elements or at least containing SEQ ID NO:15 in the promoter region and would not require undue experimentation by one skilled in the art to practice the claimed invention. It is respectfully submitted that § 112, 1st ¶, requires no more than a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims, and this requirement has clearly been met. The present record simply does not support the contention that claims 29-31, 45, 46, 56-62, 64-70 and 73-77 fail to comply with the requirements of §112, 1st ¶. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

To the extent the outstanding rejections under § 112, 1st and 2nd ¶¶, are applicable to newly added claims 78-93, Applicants respectfully submit that the foregoing remarks, comments and arguments rebut any prima facie case of lack of written description, nonenablement and indefiniteness with respect to these claims.

3. Rejection of claims 57, 65, and 75 under 35 U.S.C. 102(b).

Claims 57, 65, and 75 stand rejected under 35 U.S.C. 102(b) as being anticipated by Grattapaglia *et al.* (1995, W09519697). The Office Action asserts that the claims are drawn to an isolated and purified DNA molecule comprising a promoter fragment consisting of at least one of a cis-acting element, a box P sequence motif, a box A sequence motif or a box L sequence motif, and combinations thereof. Grattapaglia *et al.* teach a DNA sequence that exhibits 100% sequence identity to the claimed box A (SEQ ID NO:16) sequence and as such anticipates the claimed invention. Claims 57 and 75 have been cancelled. Also, claim 65 has been amended to only recite SEQ ID NO:15 not SEQ ID NO:16 thus, Grattapaglia *et al.* neither teach nor suggest the limitations recited in claim 65, as amended. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

4. Rejection of claims 57, 65, and 75 under 35 U.S.C. 102(b).

Claims 57, 65, and 75 stand rejected under 35 U.S.C. 102(b) as being anticipated by Baxter-Lowe, L.A. (1996, U.S. Patent 5,545,526). The Office Action asserts that the claims are drawn to an isolated and purified DNA molecule comprising a promoter fragment consisting of at least one of a cis-acting element, a box P sequence motif, a box A sequence motif or a box L sequence motif and combinations thereof. Baxter-Lowe teaches a DNA sequence that exhibits 100% sequence identity to the box L sequence and as such anticipates the claimed invention. Claims 57 and 75 have been cancelled. Also, claim 65 has been amended to only recite SEQ ID NO:15. not SEQ ID NO:17.

Furthermore, SEQ ID NO:17 is a plant polynucleotide sequence, while Baxter-Lowe's polynucleotide sequences are derived from humans and are used in an HLA typing method. Nothing in Baxter-Lowe teaches or suggest the limitations of claim 65 as amended. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

5. Rejection of claims 29, 31, 45-46, 54, 56-59, 61-62, 64-66, and 76-77 under 35 U.S.C. §102(b).

Claims 29, 31, 45-46, 54, 56-59, 61-62, 64-66, and 76-77 stand rejected under 35 U.S.C. 102(b) as being anticipated by Oommen *et al.* (1994, *The Plant Cell* 6:1789-1803). The Office Action asserts that Oommen *et al.* teach a DNA sequence operably linked to a GUS gene (page 1801, 4 paragraph, right column) that expresses in the vascular cylinder of alfalfa plants which comprises xylem tissue (page 1793, right column, lst ¶). The DNA sequence of Oommen *et al.* comprise at least one base pair that is essential for the proper expression and would be found in the claimed invention, and as such, Oommen *et al.* anticipate the claimed invention.

At the outset, Applicants note that the disclosure of Oommen *et al.* suggests use of the isoflavone reductase (IFR) promoter to confer different patterns of developmental expression in transgenic plants. The IFR promoter functions via the isoflavonoid branch of the phenylpropanoid pathway, not the lignin-specific branch. In fact, there is no mention at all of the 4CL transcriptional regulatory sequence in Oommen *et al.*

As set forth hereinabove, independent claims 29, 45 and 46 have been amended for clarification to recite the sequence identifiers and lignin-specific nature of the 4CL transcriptional regulatory sequence claimed in the present invention. Nothing in Oommen *et al.* teaches of suggests these limitations. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

6. Rejection of claims 29, 31, 45, 46, 54, 56-59, 61, 62, 64-70, 76, and 77 under 35 U.S.C. 102(e).

Claims 29, 31, 45, 46, 54, 56-59, 61, 62, 64-70, 76, and 77 stand rejected under 35 U.S.C. 102(e) as being anticipated by Xue *et al.* (filed Sept. 9, 1996 U.S. Patent 6,420,629). The Office Action asserts that Xue *et al.* teach an isolated DNA molecule and expression cassette comprising a 4CL promoter operably linked to an UDPG-PPase gene that is expressed in tobacco and altered the cellulose content. The Office Action further asserts that the disclosed promoter fragment would inherently contain "a transcriptional regulatory region" or a fragment of SEQ ID NO:5 and as such the claimed invention is anticipated by Xue *et al.*

Applicants submit that the disclosure of Xue *et al.* suggests an attempt to stably transform Spruce with 4CL-UDPG to achieve alleged xylem specificity. Nowhere does, Xue *et al.* disclose the polynucleotide sequence of the alleged parsley 4CL promoter sequence that was used to transform Spruce. As such, it would have been very unlikely for one skilled in the art to reproduce stable transformation in spruce as suggested in Xue *et al.* without any structural information as to the 4CL promoter. Furthermore, Xue *et al.* provides no actual test data that the use of the alleged 4CL-UDPG construct in Example 6 actually resulted in xylem-directed expression of UDPG.

As set forth hereinabove, independent claims 29, 45 and 46 have been amended for clarification to recite the sequence identifiers and lignin-specific nature of the 4CL transcriptional regulatory sequence claimed in the present invention. Nothing in Xue *et al.* teaches or suggest these specifically recited limitations Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. SUMMARY

Based on the foregoing, Applicants respectfully submit that all presently pending claims of the present application are in condition for allowance, and a favorable action thereon is respectfully requested. Should the Examiner feel that any other point requires consideration or that the form of the claims can be improved, the Examiner is invited to contact the undersigned at the number listed below.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE TO U.S. APPLICATION NO. 08/969,046 UNDER 37 CFR § 1.121

29. (Amended) An isolated and purified DNA molecule comprising a DNA segment comprising a transcriptional regulatory region of a plant 4-coumarate Co-enzyme A ligase gene, wherein the transcriptional regulatory region comprises at least SEQ ID NO:15.

31. (Amended) The isolated and purified DNA molecule of claim 29 in which the DNA segment directs expression of a linked sequence [to] in the xylem of a plant.

45. (Amended) An expression cassette comprising a transcriptional [control] regulatory region of a lignin-specific 4-coumarate Co-enzyme A ligase gene operably linked to a DNA segment comprising an open reading frame.

46. (Amended) A method of expressing a DNA segment in the xylem of a plant, comprising:

(a) introducing an expression cassette comprising a transcriptional [control] regulatory region of a lignin-specific 4-coumarate Co-enzyme A ligase gene operably linked to a DNA segment into cells of a plant.

(b) regenerating the plant cells to provide a transgenic plant; and

(c) expressing the DNA segment in the xylem of a plant.

54. (Amended) The isolated and purified DNA molecule of claim 31, wherein the linked sequence is the plant 4-coumarate Co-enzyme A ligase gene or another gene [of interest].

60. (Amended) An expression cassette as set forth in claim 45, wherein the open reading frame comprises the 4-coumarate Co-enzyme A ligase gene or another gene [DNA segment comprises an open reading frame from a gene of interest].

62. (Amended) An expression cassette as set forth in claim 45, wherein the transcriptional regulatory [control] region [is a xylem-specific gene promoter that] directs the expression of a gene in a xylem of a plant.

63. (Amended) An expression cassette as set forth in claim 45, wherein the transcriptional regulatory [control] region is a sequence as shown in SEQ ID NO: 5.

64. (Amended) An expression cassette as set forth in claim 45, wherein the transcriptional regulatory [control] region [is a promoter fragment] includes at least one of:

a) a sequence as shown in SEQ ID NO: 5, wherein SEQ ID NO: 5 comprises SEQ ID NO:15, SEQ ID NO:16, and SEQ ID NO:17;

b) a sequence as shown in SEQ ID NO: 15, SEQ ID NO:16, and SEQ ID NO:17;

c) a sequence as shown in SEQ ID NO: 15;

d) a sequence as shown in SEQ ID NO: 15, and SEQ ID NO:16;

e) a sequence as shown in SEQ ID NO: 15, and SEQ ID NO:17;

f) a sequence as shown in SEQ ID NO:16, and SEQ ID NO:17; or

g) a plant sequence as shown in SEQ ID NO:17.

65. (Amended) An expression cassette as set forth in claim [64] 45, wherein the [promoter fragment is selected from the group consisting of a cis-acting element, a box P sequence motif, a box A sequence motif or a box L sequence motif, and combinations thereof] transcriptional regulatory region comprises a sequence as shown in SEQ ID NO: 15.

73. (Amended) A polynucleotide sequence as set forth in claim 71, wherein the promoter activity is lignin-specific [is encompassed by 5' flanking region].

75. (Amended) A polynucleotide sequence as set forth in claim 71 [73], wherein [the promoter fragment] SEQ ID NO:5 comprises [is selected from the group consisting of] a cis-acting element; wherein the cis-acting element comprises SEQ IS NOs 15-17 [, a box P sequence motif, a box A sequence motif or a box L sequence motif, and combinations thereof].

76. (Amended) A gene promoter, comprising:

a polynucleotide sequence as shown [as] in SEQ ID NO: 5 [; or a promoter fragment thereof;] such that when the gene promoter is operably linked with an open reading frame [of

interest] and is integrated into a plant genomic DNA, the gene promoter targets the expression of the open reading frame [of interest to] in the xylem.